



EXPRESS MAIL LABEL NO. EL813291105US

PATENT APPLICATION  
Docket No: 7678.350.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Steven D. Jensen and Dan E. Fischer, DDS

Serial No. 09/710,181

Conf. No. 4245

Filed: November 10, 2000

For: COMPOSITIONS AND METHODS FOR  
WHITENING AND DESENSITIZING TEETH

Examiner: Raj Bawa, Ph.D.

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DECLARATION UNDER 37 C.F.R. § 1.131  
OF DAN E. FISCHER, DDS

The Assistant Commissioner of Patents  
and Trademarks  
Washington, D. C. 20231

Sir:

I, Dan E. Fischer, DDS, declare as follows:

1. I am one of the named co-inventors of the subject matter disclosed and claimed in the above-identified application, and I am personally knowledgeable of the facts stated herein.
2. Steven D. Jensen is the other named co-inventor of the subject matter disclosed and claimed in the above-identified application.
3. The above-identified application has been assigned to Ultradent Products, Inc. ("Ultradent"), located at 505 West, 10200 South in South Jordan, Utah.

4. The subject matter claimed in the above-identified application is the result of a joint effort between me and Steven D. Jensen.

5. I obtained a doctorate of dental surgery from Loma Linda University, located in Loma Linda, California, in 1974, am currently the president of Ultradent, and continue to practice dentistry in addition to my duties as President of Ultradent, therefore making me knowledgeable in the field of dentistry.

6. The above-identified application discloses and claims desensitizing dental bleaching compositions that comprise a dental bleaching agent, such as carbamide peroxide, and potassium nitrate as a desensitizing agent, both of which are dispersed in an appropriate carrier.

7. Potassium nitrate is known to be an effective desensitizing agent for teeth, as described and claimed in U.S. Patent Nos. 5,851,512 and 5,855,870, both of which are assigned to Ultradent Products, Inc. and which name Steven D. Jensen and myself as co-inventors (Mr. Jensen having been added as a co-inventor after issuance).

8. A desensitizing dental composition containing 3% by weight potassium nitrate, used to alleviate sensitivity associated with home-use dental bleaching compositions, and covered by U.S. Patent Nos. 5,851,512 and 5,855,870, is available from Ultradent Products, Inc. under the trade name ULTRA EZ.

9. It is my understanding, as one knowledgeable in the field of dentistry, that the standard concentration of potassium nitrate within desensitizing dental compositions is about 3-5% by weight.

10. Subsequent to the filing of U.S. Patent Nos. 5,851,512 and 5,855,870, it was discovered that potassium nitrate can, in some cases, when included within a dental bleaching composition in certain concentrations, also enhance the whitening ability of a dental bleaching composition compared to bleaching compositions that do not include potassium nitrate, as described

in U.S. application Serial No. 09/494,113, filed January 31, 2000, now abandoned, in addition to providing a desensitizing effect.

11. Although it is and has been customary to include at least 3% potassium nitrate within desensitizing dental compositions, we discovered, by means of an extensive comparative study summarized in the above-identified application, that potassium nitrate, when included within a dental bleaching composition at concentration of only 0.5% by weight, unexpectedly and surprisingly provides significantly higher degrees of both desensitization and whitening compared to compositions that include either 3% potassium nitrate or no potassium nitrate.

12. As set forth at page 26, line 1, through page 29, line 4, of the above-identified application, five (5) dental bleaching compositions (identified as compositions A-E, respectively) having the following amounts of carbamide peroxide and potassium nitrate were prepared and comparatively tested:

<u>Composition</u>	<u>Carbamide Peroxide</u>	<u>KNO<sub>3</sub></u>
A	10%	0%
B	10%	3%
C	10%	3%
D	15%	3%
E	10.5%	0.5%

13. The results of the comparative study were summarized in the following table found at page 28, lines 1-17, of the above-identified application, with a description of what is meant by each column of data provided beneath the table:

0% KNO<sub>3</sub>  
3% KNO<sub>3</sub>  
0.5% KNO<sub>3</sub>

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

14. As indicated by the data set forth in ¶13 above, the comparative study also surprisingly and unexpectedly indicated that potassium nitrate, when included in a concentration of 3% by weight within dental bleaching compositions having 10% or 15% by weight carbamide peroxide (compositions B-D), actually caused *increased sensitivity*, on average, to hot or cold, as well as greater tongue sensitivity, compared to composition A, which included 10% carbamide peroxide and *no* potassium nitrate.

15. The comparative study thus demonstrated the surprising and unexpected result that potassium nitrate, when blended with a dental bleaching agent in a dental bleaching composition used to bleach teeth, does not behave as a desensitizing agent at all concentrations, particularly at higher concentrations such as 3%.

16. Because potassium nitrate was known to be a desensitizing agent, and is customarily included in amounts of about 3-5% within desensitizing dental compositions, one of ordinary skill in the art, when reading U.S. Patent Nos. 5,851,512 and 5,855,870, which teach the inclusion of a

dental bleaching agent together with potassium nitrate in a single composition to both bleach and desensitize teeth in a single step, would have expected potassium nitrate to provide desensitizing properties within the standard concentration range of about 3-5%.

17. However, the comparative study, as summarized in the above-identified application, demonstrated the entirely counterintuitive and surprising result of potassium nitrate providing much greater desensitization when used within a dental bleaching composition at a concentration of only 0.5% compared to when it was included in a concentration of 3%.

18. Even more surprisingly and unexpectedly, the dental bleaching composition that included 0.5% potassium nitrate and 10.5% carbamide peroxide (composition E) also provided significantly better whitening of teeth compared to compositions that included either no potassium nitrate (composition A) or 3% potassium nitrate (compositions B-D), even better than composition B, which included 3% potassium nitrate and a higher concentration of carbamide peroxide (15%).

19. In particular, the composition that included 0.5% potassium nitrate (composition E) resulted, on average, in a total of 8.9 shade tab changes during the duration of the study, whereas the composition that included no potassium nitrate (composition A) resulted, on average, in a total of 5.4 shade tab changes, while the compositions that include 3% potassium nitrate (compositions B-D) resulted, on average, in a total of 4.6, 6.7 and 7.5 shade tab changes, respectively.

20. In summary, the comparative study demonstrated the superiority of including 0.5% potassium nitrate within a desensitizing dental bleaching composition compared to either including no potassium nitrate or 3% potassium nitrate, in terms of significantly decreased tooth sensitivity and significantly increased tooth whitening, both of which were surprising and unexpected based upon conventional knowledge at the time of the invention.

21. For example, Den-Mat, Inc. currently sells, and, on information and belief, has sold since before the filing date of the above-identified application, a dental bleaching gel that includes


a dental bleaching agent and potassium nitrate in an amount of about 5% by weight under the trade name REMBRANDT XTRA COMFORT, as indicted by an advertisement in the Dental Products Report published in November 1998.

22. In order to determine the actual concentration of potassium nitrate, a commercially available sample of REMBRANDT XTRA COMFORT was obtained and analyzed, as was a sample of Ultradent's own 0.5% potassium nitrate dental bleaching composition currently sold under the name of OPALESCENCE PF in order to confirm the accuracy of the testing method.

23. As evidenced by the analysis summarized in Exhibit A attached hereto, it was determined that REMBRANDT XTRA COMFORT includes 17% by weight carbamide peroxide and 5.17% by weight potassium nitrate, which is about 2-1/2 times greater than the upper range limit of "about 2% by weight" potassium nitrate recited in the broadest claim of the above-identified application, about 5 times greater than the upper limit of the more preferred range ("about 1% by weight"), and about 10 times greater than the most preferred amount of "about 0.5% by weight" potassium nitrate.

24. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at Salt Lake City, Utah, this 5 day of June 2001.

  
Dan E. Fischer, D.D.S.



## II. Analyses Performed:

Samples AD 2869 were analyzed for % carbamide peroxide (CPO) using procedure TST 21.4. Samples AD 2869 were analyzed for % sodium fluoride using TST 52.4. Fluoride ( $F^-$ ) content was recorded as sodium fluoride (NaF). Nitrate ( $NO_3$ ) determination was done on all samples by IC using the Shimadzu system. The nitrate concentration was recorded as potassium nitrate ( $KNO_3$ ). Opalescence PF 20% Melon was analyzed as a control sample. Each product was analyzed at least twice for tests performed and tests were analyzed from different syringes.

## III. Results:

Product	Peroxide Results	Label Claim	Fluoride Results	Label Claim	Nitrate Results
Rembrandt (AD 2869)	17.0% (m/m) CPO	16% CPO	N/A	N/A	5.17% (m/m) $KNO_3$
Opalescence PF 20% Melon Batch: FKABF W/O#: W43QH	19.9% (m/m) CPO	20% CPO	0.2562% (m/m) NaF	0.11% $F^-$ 0.25% NaF	0.48% (m/m) $KNO_3$ 0.50% (m/m) Claim

Reviewed by: Fareed Ansari

Signature: *Fareed Ansari*

Date: 5/25/01

Analyst: Anna Lee Wilson/ Fred Williams

Signature: *Anna Lee Wilson*

Signature: *Fred Williams*

Book #: 1239 Page #: 24, 27, 28, 29

Book#: 1281 Page #: 2, 8, 15

Date: 5/25/01